MAY - 5 2000

K001310

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (716) 453-4041 Contact Person: Marlene A. Shulman
2.	**Preparation date**	Date Special 510(k) prepared: April 24, 2000
3.	**Device name**	Trade or Proprietary Name: VITROS Chemistry Products CREA Slides VITROS Chemistry Products Calibrator Kit 1 Common Name : Creatinine Classification Name: Creatinine test system (21 CFR 862.1225, Class II).
4.	**Predicate device**	The VITROS Chemistry Products CREA Slides (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to the VITROS Chemistry Products CREA Slides (current slide) and VITROS Chemistry Products Calibrator Kit 1.

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5. Device description

The VITROS Chemistry System uses VITROS Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multilayered analytical element of a VITROS Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of chemistry products (in this case VITROS Chemistry Products CREA Slides, VITROS Chemistry Products Calibrator Kit 1) which are combined by the VITROS Chemistry System to perform the VITROS CREA test.

2. The VITROS Chemistry System – instrumentation, which provides automated use of the chemistry slides. Multiple VITROS Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K890928, K890929, K922072, K946090 and K922072).

Common reagent used by the VITROS System. The VITROS Chemistry Products 7% BSA was cleared by a previous 510(k) pre-market notification (K903071).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS CREA Slides
For in vitro diagnostic use only.
VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in the calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and URIC.

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510(k) Summary, Continued

7. Comparison to predicate device

The VITROS Chemistry Products CREA Slide (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to VITROS Chemistry Products CREA Slide for use with human serum, plasma, and urine which was cleared by the FDA (K861819, June 11, 1985) for in vitro diagnostic use.

Table 1 lists the characteristics of the tests performed using the VITROS CREA Slide (modified) and the VITROS CREA Slide(current).

Table 1 List of Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS CREA Slide (Modified)	Predicate Device VITROS CREA Slide (Current)
Sample volume	6 µL	10 µL
Quantity of Reactive Ingredients per slide (test)	Creatinine amidohydrolase (Flavobacterium sp., E.C.3.5.2.10): 0.18 U; Creatine amidinohydrolase (Flavobacterium sp., E.C.3.5.3.3): 4.27 U; Sarcosine oxidase (Bacillus sp., E.C.1.5.3.1): 0.50 U; Peroxidase (horseradish root, E.C.1.11.1.7): 1.40 U; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye): 0.03 mg.	Creatinine amidohydrolase (Flavobacterium sp., E.C.3.5.2.10): 0.26 U; Creatine amidinohydrolase (Flavobacterium sp., E.C.3.5.3.3): 6.09 U; Sarcosine oxidase (Bacillus sp., E.C.1.5.3.1): 0.71 U; Peroxidase (horseradish root, E.C.1.11.1.7): 1.99 U; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye): 0.04 mg.
Concentrations of Slide Reactive Ingredients per cm-squared	No Change.	Creatinine amidohydrolase (Flavobacterium sp., E.C.3.5.2.10): 0.20 U; Creatine amidinohydrolase (Flavobacterium sp., E.C.3.5.3.3): 4.70 U; Sarcosine oxidase (Bacillus sp., E.C.1.5.3.1): 0.55 U; Peroxidase (horseradish root, E.C.1.11.1.7): 1.60 U; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye): 0.032 mg.
Intended Use	No change.	For in vitro diagnostic use only. VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.
Basic principle	No Change.	Dry, multilayered slide utilizing reflectance spectrophotometry
Sample type	No Change.	Serum, plasma, urine
Assay Range Serum, Plasma Urine	 No Change. No Change.	 Serum/Plasma: 0.05-14.0 mg/dL Urine: 0.05-16.5 mg/dL
Instrumentation	No Change.	VITROS 250, 500, 750 and 950 Series Analyzers
Incubation time and temperature	No Change.	3.85 and 5 minutes at 37°C

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8. Conclusions

The information presented in the pre-market notification demonstrate that the performance of the VITROS CREA Slides (modified) for use with human serum, plasma, and urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured creatinine values spanning the assay range.

The information presented in this premarket notification provide a reasonable assurance that the VITROS CREA Slides (modified) for use with human serum, plasma, and urine is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2000

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626

Re: K001310
Trade Name: VITROS Chemistry Products CREA Slides
VITROS Chemistry Products Calibrator Kit 1
Regulatory Class: II
Product Code: CGX, JIX
Dated: April 24, 2000
Received: April 25, 2000

Dear Ms. Shulman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): _____

Device Name:
VITROS Chemistry Products CREA Slides
VITROS Chemistry Products Calibrator Kit 1

Intended Use:

VITROS Chemistry Products CREA Slides
For in vitro diagnostic use only.
VITROS CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in the calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and Uric.

Summary and Explanation of Test:

Serum creatinine and urinary creatinine excretion is a function of lean body mass in normal persons and shows little or no response to dietary changes. Since urine creatinine is excreted mainly by glomerular filtration, with only small amounts due to tubular secretion, serum creatinine and a 24-hour urine creatinine excretion can be used to estimate the glomerular filtration rate. Serum creatinine is increased in acute or chronic renal failure, urinary tract obstruction, reduced renal blood flow, shock, dehydration, and rhabdomyolysis. Causes of low serum creatinine concentration include debilitation and decreased muscle mass. Exercise may cause an increased creatinine clearance. The creatinine clearance rate is unreliable if the urine flow is low.

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001310

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)